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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	16

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/202,681	Mathur et al.
Examiner	**Art Unit**
Richard Hutson	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1 136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1 704(b).

Status

1) X Responsive to communication(s) filed on Feb 5, 2001

2a) ___ This action is FINAL. 2b) X This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) X Claim(s) 1-12 is/are pending in the applica

4a) Of the above, claim(s) ___ is/are withdrawn from considera

5) X Claim(s) 12 is/are allowed

6) X Claim(s) 1-11 is/are rejected.

7) ___ Claim(s) ___ is/are objected to.

8) ___ Claims ___ are subject to restriction and/or election requirem

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ___ is/are objected to by the Examiner

11) The proposed drawing correction filed on ___ is a) approved b) disapproved

12) ___ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of

1 Certified copies of the priority documents have been received

2 Certified copies of the priority documents have been received in Application No ___

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17 2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) X Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e)

Attachment(s)

15) X Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ___

18) Interview Summary (PTO 413) Paper No(s) ___

19) Notice of Informal Patent Application (PTO 152)

20) Other

DETAILED ACTION

1. Applicants amendment of claim 12 in paper No: 9, filed 9/18/2000. Claims 1-12 are still at issue and are present for examination.

2. Applicants' arguments filed on 9/18/2000, paper No. 9, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

3. Applicant's election with traverse of the sequence of SEQ ID NO: 19 (and the those polynucleotides which encode SEQ ID NO: 28) is acknowledged. The traversal is on the ground(s) that coexamination of all of species, SEQ ID NOs: 19-27 and 43 (and the those polynucleotides which encode SEQ ID NOs: 28) would not require unduly burden the Examiner because the sequences could be searched and then similar art could be searched for functional similarity. Applicants further point out that according to the MPEP 803.04, "...up to ten independent and distinct nucleotide sequences will be examined..." This is not found persuasive because while the searches for the species do overlap, they are not coextensive. Further, the MPEP states **up to ten** independent and distinct nucleotide sequences, not a minimum of ten, and further included with the search of each elected species is not only the elected SEQ ID NO:, but those polynucleotides which encode the amino acids encoded by the elected species, listed as additional SEQ ID NOs.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

4. Claims 5, 10 and 11 are objected to because of the following informalities:

5. Claim 5 has a "period" after (a), line 11. It is believed that the proper punctuation should be "coma".

6. Claim 5 (c) recites "...at least 15 bases of the polynucleotide of (a) **and** (b)." This should recite "...at least 15 bases of the polynucleotide of (a) **or** (b)."

7. Claims 10 and 11 reeite "... a portion is coded for by a polynucleotide..." Polynucleotides "encode" proteins they do not "code" for proteins.

8. Claim 11 further recites "... set forth **in in** SEQ ID NOS:..." This should recite "... set forth **in** SEQ ID NOS:..." Appropriate correetion is required.

9. Claim 10 (b) and 11(b) reeite "...at least 30 amino acid residues **to** the enzyme of (a)..." They should recite "...at least 30 amino acid residues **of** the enzyme of (a)..."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subjeet matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention

Claims 1-9 are drawn to an isolated polynucleotide (DNA or RNA) selected from the group consisting of: (a) a polynucleotide encoding an enzyme comprising an amino acid sequence selected from the group selected from the group of amino acid sequences set forth in SEQ ID NOs: 28-36; (b) a polynucleotide which is complementary to the polynucleotide of (a); and **(c) a polynucleotide comprising at least 15 bases of the polynucleotide of (a) or (b),** vectors and host cells comprising and methods using said polynucleotide (claims 1, 3, 4, 6, 7, 8 and 9), **fragments of at least 15 bases in length that will hybridize to the DNA** which encodes SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52 or 54 (claim 2), and a polynucleotide comprising a polynucleotide having at least 70% identity to a member selected from the group consisting of (a) a polynucleotide encoding an enzyme encoded by the DNA contained in ATCC Deposit No: 97379, wherein said enzyme is selected from a specific bacterial species, a polynucleotide complementary to the polynucleotide of (a) and **(c) a polynucleotide comprising at least 15 bases of the polynucleotide of (a) and (b).** Claims 10 and 11 are drawn enzymes of which at least a portion is coded for by a polynucleotide of claim 1, and which is selected from the group consisting of: (a) an **enzyme comprising an amino acid sequence which is at least 70% identical** to an amino acid sequence selected from the group of amino acid sequences set forth in SEQ ID NOs: 28-36 and (b) an **enzyme which comprises at least 30 amino acid residues** to the enzyme of (a) (claim 10), an enzyme comprising an amino acid sequence selected from the group

of amino acid sequences set forth in in SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52, or 54; and (b) **an enzyme which comprises at least 30 amino acid residues** to the enzyme of (a). The specification, however, only provides the representative species of claimed protcins and polynucleotides represented by SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52, or 54 and the polynucleotides which encode these proteins. There is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification also fails to describe additional representative species of these proteins, DNAs, host cells and methods by any identifying structural characteristics or properties other than the characteristics recited in claims, for which no predictability of function is apparent.

The genus of proteins, DNAs and host cells that are claimed is a large variable genus with potentiality of comprising or encoding many different proteins. Therefore, many functionally unrelated DNAs, proteins, host cells and methods are encompassed within the scope of these claims. The specification discloses the species encompassed by SEQ ID NOs: 19-54 of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus which reads on not only all naturally occurring thermostable phosphatases and their encoding nucleic acids, but also on mutant thermostable phosphatases as well as enzymes of undisclosed function and their encoding nucleic acids. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

11. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for proteins having the amino acid sequence of SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52, or 54 and enzymatically active fragments thereof, as well as polynucleotides which encode these proteins, does not reasonably provide enablement for any isolated polynucleotide selected from the group consisting of: (1) a polynucleotide comprising at least 15 bases of the polynucleotides that encode SEQ ID NOs: 28-36, (2) fragments of at least 15 bases in length that will hybridize DNAs which encode SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52 or 54 (3) polynucleotides comprising a polynucleotide having at least 70% identity to a polynucleotide comprising at least 15 bases of the a polynucleotide of member selected from ATCC Deposit No: 97379 or its complement nor any enzyme of which at least a portion is coded for by a polynucleotide of claim 1, and which is selected from the group consisting of: (a) an enzyme comprising an amino acid sequence which is at least 70% identical to an amino acid sequence selected from the group of amino acid sequences set forth in SEQ ID NOs: 28-36 and (b) an enzyme which comprises at least 30 amino acid residues to the enzyme of (a). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-9 are so broad as to encompass any isolated polynucleotide (DNA or RNA) selected from the group consisting of: (1) **a polynucleotide comprising at least 15 bases of the polynucleotides that encode** SEQ ID NOs: 28-36, (2) **fragments of at least 15 bases in length that will hybridize DNAs** which encode SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52 or 54 (3) polynucleotides comprising a polynueleotide having at least 70% identity to a **polynucleotide comprising at least 15 bases of the a polynucleotide of** member selected from ATCC Deposit No: 97379 or its complement. Claims 10 and 11 are so broad as to encompass any enzyme of which at least a portion is coded for by a polynueleotide of claim 1, and which is selected from the group consisting of: (a) an **enzyme comprising an amino acid sequence which is at least 70% identical** to an amino acid sequence selected from the group of amino acid sequences set forth in SEQ ID NOs: 28-36 and (b) an **enzyme which comprises at least 30 amino acid residues** to the enzyme of (a). The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNAs host cells, enzymes and methods broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidanee with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its funetion. However, in this

case the disclosure is limited to the proteins having the amino acid sequence of SEQ ID NOs: 28-36, 42, 44, 46, 48, 50, 52, or 54 and the polynucleotides which encode these proteins.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions. Further still, the claim should be so limited that the activity/utility desired is known to one of skill in the art, as many of the rejected claims have no such limitation.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any polynucleotide and protein with the claimed limitations because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting the desired activity (provided this is a limitation of the claim); (B) the general tolerance of thermostable phosphatases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid modifications of any thermostable phosphatase. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those polynucleotides and proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claim 1, 3, 5, 6, 7, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Hirschberg et al. (U.S. Patent No: 5,792,903).

Hirschberg et al. teach a purified and isolated DNA sequence encoding lycopene cyclase. The cDNA taught by Hirschberg et al. is a 4928 base pair sequence of DNA with an open reading

frame from 2029-3261 of SEQ ID NO: 1. Hirschberg et al. teach approximately 2000 bp of sequence upstream of the lycopene cyclase open reading frame and included in this region is a region from nucleotide 1506 to 1522 (17 nucleotides) that is 100 % identical to SEQ ID NO: 19 and thus Hirschberg et al. teach an isolated polynucleotide comprising at least 15 bases of a polynucleotide encoding an enzyme comprising an amino acid sequence as set forth in SEQ ID NO: 28. Hirschberg et al. also teach this DNA in a vector and host cell thus claims 1, 3, 5, 6, 7, 8 and 9 are anticipated.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on M-F from 7:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapy Achutamurthy (Murthy), can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Rebecca Prouty

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Richard Hutson Ph.D.
4/11/2001